**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

**CHARLESTON DIVISION**

**IN RE: BOSTON SCIENTIFIC CORP.,**
**PELVIC REPAIR SYSTEM**
**PRODUCTS LIABILITY LITIGATION** **MDL No. 2326**

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**THIS DOCUMENT RELATES TO THE FOLLOWING CASE:**

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| HANNA WILKERSON,<br>Plaintiff,<br>vs.<br>BOSTON SCIENTIFIC CORPORATION,<br>Defendant. | Civil Action No. 2:13-cv-04505 |

**BOSTON SCIENTIFIC CORPORATION'S MOTION FOR PARTIAL SUMMARY JUDGMENT ON PLAINTIFF HANNA WILKERSON'S PUNITIVE DAMAGES CLAIM AND MEMORANDUM IN SUPPORT**

## INTRODUCTION

Plaintiff Hanna Wilkerson brings this product liability action against Boston Scientific Corporation ("Boston Scientific") alleging that Boston Scientific's implantable pelvic mesh medical device — the Advantage Fit System — was defective and caused her personal injury. In addition to the lack of support for her substantive claims, Plaintiff's claim for punitive damages is also without evidentiary or legal support. For the reasons discussed in the incorporated Memorandum, Boston Scientific respectfully moves the Court for an order granting partial summary judgment on Plaintiff's punitive damages claim.

## STATEMENT OF MATERIAL FACTS

1. Plaintiff is a citizen and resident of North Carolina. Short Form Complaint ("SFC")[1] at ¶ 4.

2. The first synthetic mid-urethral sling for the treatment of Stress Urinary Incontinence ("SUI"), the Tension-Free Vaginal Tape ("TVT"), was developed by Ulmsten, et al. in 1996.[2]

3. Six years later, on April 3, 2002, Boston Scientific obtained FDA clearance of its first mid-urethral slings, the Advantage, the Advantage Fit, and the Lynx devices. *See* FDA Clearance Letter.[3]

4. Advantage is a Type I, monofilament, macroporous polypropylene mesh. The Advantage Fit is made from the same Type 1 polypropylene mesh as the Advantage and uses the same retropubic approach but incorporates design improvements.

5. Prior to the FDA's clearance in 2002, a body of clinical literature existed establishing the safety and efficacy of polypropylene mid-urethral slings and their superiority over other surgical treatment options such as the Burch procedure.[4]

6. Several studies consisting of long term data confirm the safety, efficacy, and superiority of polypropylene mid-urethral slings.[5]

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[1] A true and correct copy of the Short Form Complaint is attached to the Motion as Exhibit A.

[2] Ulmsten U, Hendriksson L, Johnson P, Varhos G. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. *Int Urogynecol J* 1996;7:81–6.

[3] A true and correct copy of the FDA Clearance Letter is attached to the Motion as Exhibit B.

[4] Ulmsten, U, et al., A three-year follow up of tension-free vaginal tape for surgical treatment of female stress urinary incontinence. *Br J Obstet Gynaecol* (April 1999), v106, pp345-50. Olsson, I, et al., A three-year postoperative evaluation of tension-free vaginal tape. *Gynecol and Obstet Invest* (1999); 48:267-69. Merlin, T, et al. A systematic review of tension-free urethropexy for stress urinary incontinence: intravaginal slingplasty and the tension-free vaginal tape procedures. *BJU Int* (2001), 88, 871-80. Liapsis, A, et al. Burch colposuspension and tension-free vaginal tape in the management of stress urinary incontinence in women. *European Urology*, 41 (2002) 469-73.

[5] Nilsson, C, et al., Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. *Int Urogynecol J* (2013) 24:1265-69. Liapsis, A, et al., Efficacy of inside-out transobturator vaginal tape (TVTO) at 4 years follow-up. European J of Obstet & Gynecol and Repod Biology 148 (2010) 199-201.

7. The FDA provides a discussion of requirements for 510(k) applications in its Guidance for the Preparation of Premarket Notification Applications for a Surgical Mesh, which does not require submitting the Material Safety Data Sheets ("MSDS").[6]

8. The MSDS[7] was authored in 2004 by Phillips Sumika, the resin provider, and contained the following statement regarding medical application: "[d]o not use . . . material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues."

9. Boston Scientific submitted the 2004 MSDS containing the medical application caution with the Pinnacle 510(k) application in July of 2007. *See* Pinnacle Abbreviated 510(k) July 12, 2007, p. 38.[8]

10. The FDA subsequently approved the Pinnacle for market in 2007 even with knowledge of the medical caution in the MSDS. [9]

11. Boston Scientific again voluntarily submitted the MSDS with its Uphold 510(k) application in 2008. *See* Pinnacle II Abbreviated 510(k) April 11, 2008, pp. 30-39.[10]

12. The FDA requested additional information regarding the MSDS after receiving the Uphold 510(k) application. Boston Scientific received a letter from the FDA dated June 17, 2008, with Question No. 8 asking:

> [t]he material safety data sheet (MSDS) provided for the Marlex material states that the product use is for coatings. In this MSDS there is a medical application caution that states 'do not use this Chevron Phillips Chemical Company LP

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Waltregny, D, et al., TVT-O for the treatment of female stress urinary incontinence: results of a prospective study after a 3-year minimum follow-up. European Urology 52 (2008) 401-410.

[6] A true and correct copy of Guidance for the Preparation of a Premarket Notification Applications for a Surgical Mesh is attached to the Motion as Exhibit C.

[7] A true and correct copy of the 2004 MSDS is attached to the motion as Exhibit D.

[8] A true and correct copy of the Pinnacle Abbreviated 510(k) July 12, 2007 MSDS is attached to the Motion as Exhibit E.

[9] A true and correct copy of the FDA 510(k) Pinnacle Clearance Letter is attached to the Motion as Exhibit F.

[10] A true and correct copy of the Pinnacle II Abbreviated 510(k) April 11, 2008 MSDS is attached to the Motion as Exhibit G.

> material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.' Please provide a rationale why your mesh material is safe for use as a permanent implant device contrary to what is stated in the MSDS provided for the Marlex material.

*See* FDA Letter June 17, 2008.[11]

13. Boston Scientific responded to the question, discussing the history with Marlex, as well as its battery of biocompatibility and physical characteristic testing, and an animal test assessing the safety of the polypropylene. *See* Boston Scientific Response to FDA Question #8 ("Response to #8").[12] Both Pinnacle's Polyform and Advantage Fit make use of the same polypropylene resin that Boston Scientific has been using in surgical implants since the 1990s. *Id*.

14. The FDA cleared the Uphold for market in August of 2008 with full knowledge of the MSDS, including the application caution.[13]

15. Boston Scientific was transparent with its resin supplier, Phillips Sumika, about its intended use of their resin to manufacture medical devices for permanent implantation in the human body. Phillips Sumika ultimately agreed to sell a contracted amount of resin to Boston Scientific. Boston Scientific and Phillips Sumika entered into an effective contract on October 1, 2004, signed in March 2005. The contract made clear that Boston Scientific may purchase Phillips Sumika polypropylene resin "for use by, for, or on behalf of Boston Scientific in the manufacture of medical devices which may be implanted in the human body or have contact with internal body fluids or tissues ("Medical Devices")." *See* October 1, 2004 Agreement.[14]

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[11] A true and correct copy of the FDA Letter June 17, 2008 is attached to the Motion as Exhibit H.
[12] A true and correct copy of Boston Scientific's Response to FDA Question # 8 is attached to the Motion as Exhibit I.
[13] A true and correct copy of the FDA 510(k) Uphold Clearance Letter is attached to the Motion as Exhibit J.
[14] A true and correct copy of the October 1, 2004 Agreement is attached to the Motion as Exhibit K.

16. Six years after the FDA cleared Boston Scientific's mid-urethral slings for market and before the surgery at issue in this case, on October 20, 2008, the FDA issued an FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence ("2008 FDA PHN").[15]

17. This 2008 FDA PHN stated that "[t]he most frequent complications included erosion through the vaginal epithelium, infection, pain, urinary problems, and recurrence of prolapse and/or incontinence. . . . Treatment of the various types of complications included additional surgical procedures (some of them to remove the mesh)." *Id.*

18. Boston Scientific used a 2010 Stress Urinary Incontinence Patient Education Brochure, which also included a list of potential adverse events.[16]

19. Directions For Use ("DFUs")[17] are included with each product, which in addition to identifying potential complications, encourages doctors to consult medical literature regarding techniques, complications and hazards associated with the intended procedures for additional information.

20. Boston Scientific went steps further and took information regarding the Advantage Fit System, and other Boston Scientific devices, to the public when it launched its Pelvic Floor Institute website in January 2010.[18]

21. Dr. Kelly A. Booth, Plaintiff's implanting physician, was aware of the potential risks associated with use of the Advantage Fit System sling before Plaintiff's surgery based on

[15] A true and correct copy of the 2008 FDA PHN is attached to the Motion as Exhibit L.
[16] A true and correct copy of the applicable patient brochure is attached to the Motion as Exhibit M.
[17] A true and correct copy of the Advantage Fit System Directions For Use is attached to the Motion as Exhibit N.
[18] *See* http://www.bostonscientific.com/templatedata/imports/HTML/PFI/PFI_bridge.html (last visited Jan. 11, 2015).

her years of clinical experience and training. Deposition of Dr. Kelly A. Booth ("Dr. Booth Dep.")[19] at 84:3-85:4, 85:9-20.

22. Prior to the procedure, Dr. Booth extensively reviewed the risks of bleeding, infection, damage to surrounding organs including bladder, bowel, and ureters. *See* Dr. Booth Dep. at 36:23-37:25, 40:7-41:1, 42:20-47:4; Kelly A. Booth, M.D. ("BOOTHK MEDICAL Records")[20] at BOOTHK_MEDICAL_18. Dr. Booth also reviewed the risk of recurrent stress incontinence, recurrent prolapse, mesh erosion, and urinary retention. *See id.*

23. On March 9, 2010, Plaintiff underwent surgery that involved the implant of the Advantage Fit System. SFC at ¶¶ 9, 10; *see also* Carolinas Medical Center, NorthEast ("CMCNE Records")[21] at CMCNE Medical 42-43; Dr. Booth Dep. at 49:25-52:23.

24. The Advantage Fit System was implanted to treat Plaintiff's stress urinary incontinence. SFC at ¶ 9; Dr. Booth Dep. at 39:23-40:1.

25. The surgery took place at Carolinas Medical Center, NorthEast in Concord, North Carolina. SFC at ¶ 11.

26. Dr. Booth believes that TVT, such as the Advantage Fit System, is the "gold standard" for treating stress urinary incontinence. Dr. Booth Dep. at 19:8-20:17. She continues to offer mesh as a treatment option to her patients even today. *Id.* at 83:15-24.

27. Following its Safety Communication Update, issued on July 13, 2011 ("2011 FDA Update"),[22], the FDA held an Obstetrics & Gynecology Devices Panel on September 8-9, 2011. This Panel concluded after deliberation that for mid-urethral slings, like the Advantage Fit

[19] A true and correct copy of excerpts of Dr. Booth's deposition is attached to the Motion as Exhibit O.
[20] True and correct copies of the relevant Kelly A. Booth, M.D. records are attached to the Motion as Exhibit P.
[21] True and correct copies of the relevant Carolinas Medical Center- NorthEast Medical Records are attached to the Motion as Exhibit Q.
[22] *See* FDA Safety Communication: Update on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse, July 13, 2011, http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm262435.htm (last visited Jan. 11, 2015).

System, the safety and effectiveness is well-established.[23] The Panel also determined that no further testing or special monitoring through 522 post-market studies was necessary. *Id*. With regard to efficacy, the Panel found mesh sling surgeries for SUI were successful in approximately 70-80% of women at one year post-op, which was similar to outcomes reported following other surgical treatment options for SUI. *Id*.

28. On January 3, 2014, AUGS, in conjunction with the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction ("SUFU"), issued a position statement supporting the use of mid-urethral slings in the surgical treatment of SUI and declared them to be the recognized worldwide standard of care:

> The polypropylene mesh mid-urethral sling is the recognized worldwide standard of care for the surgical treatment of stress urinary incontinence. The procedure is safe, effective, and has improved the quality of life for millions of women.

*See* Position Statement on Mesh Mid-Urethral Slings for Stress Urinary Incontinence at 1 ("2014 Position Statement").[24]

29. The impetus behind the 2014 Position Statement was the organizations' concern that, following the FDA's PHN, plaintiffs' lawyers' advertisements inappropriately targeted women who received polypropylene mid-urethral slings for treatment of SUI and resulted in "confusion, fear, and an unbalanced negative perception regarding the mid-urethral sling as a treatment option for SUI." *Id*. AUGS and SUFU stated that this "negative perception" is not shared by the medical community, the FDA, or the "overwhelming majority of women who have been satisfied with their mid-urethral slings." *Id*.

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[23] *See* Surgical Mesh Panel Meeting Summary. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/UCM271769.pdf (last visited Jan. 11, 2015).

[24] A true and correct copy of the 2014 Position Statement on Mesh Mid-Urethral Slings for Stress Urinary Incontinence is attached hereto as Exhibit R.

30. The 2014 Position Statement further notes the use of monofilament polypropylene mid-urethral slings to treat SUI is supported by "a broad evidence base including high quality scientific papers in medical journals in the US and the world." *Id*. at 2. Indeed, there are over 2,000 publications describing mid-urethral slings in the treatment of SUI which demonstrate clinical effectiveness, patient satisfaction, and superior efficacy and safety as compared to other SUI surgical procedures. *Id*. Mid-urethral slings, such as the Advantage, have been "extensively-studied," "are safe and effective relative to other treatment options," and "remain the leading treatment option and current gold standard for stress incontinence surgery." *Id*. In fact, the polypropylene mid-urethral sling "is probably the most important advancement in the treatment of stress urinary incontinence in the last 50 years and has the full support of our organizations which are dedicated to improving the lives of women with urinary incontinence." *Id*. at 3.

31. The American Urological Association ("AUA") also supports the use of polypropylene mid-urethral slings as a safe and effective treatment option for SUI. In 2009, AUA issued a report describing the safety and efficacy of surgical procedures for the treatment of SUI. *See* Guideline for the Surgical Management of Female Stress Urinary Incontinence: 2009 Update.[25] Data was collected from a meta-analysis of 436 articles on the treatment of SUI published from 2002 through 2005. *Id*. at 9. The meta-analysis found the cure rate in women with SUI who received a mid-urethral sling was comparable to the cure rate in women who underwent Burch procedures and autologous fascial slings. *Id*. at 26.

32. Like AUGS, the AUA also released a Position Statement following the FDA's 2011 Safety Communication. *See* AUA Position Statement on the Use of Vaginal Mesh for the

[25] A true and correct copy of the Guideline for the Surgical Management of Female Stress Urinary Incontinence: 2009 Update is attached to the Motion as Exhibit S.

Surgical Treatment of Stress Urinary Incontinence.[26] AUA supported the use of polypropylene mid-urethral slings for the treatment of SUI because they offer improved patient outcomes and reduced hospitalization:

> Extensive data exist to support the use of synthetic polypropylene mesh suburethral slings for the treatment of female SUI, with minimal morbidity compared with alternative hospitalization, and reduced voiding dysfunction. Advantages include shorter operative time/anesthetic need, reduced surgical pain, reduced hospitalization, and reduced voiding dysfunction. Mesh-related complications can occur following polypropylene sling placement, but the rate of these complications is acceptably low. *Id.*

The efficacy of polypropylene mid-urethral slings for SUI at 5-10 years is supported by "multiple case series and randomized controlled trials" and is "equivalent or superior to other surgical techniques." *Id.* Further, there is "no significant increase in adverse events observed over this period of follow-up." *Id.* AUA re-endorsed its conclusions from the 2009 Guideline and opined that "any restriction of the use of synthetic polypropylene mesh suburethral slings would be a disservice to women who choose surgical correction of SUI." *Id.*

33. Plaintiff filed this lawsuit against Boston Scientific on May 6, 2013, seeking compensatory and punitive damages. *See* SFC; Master Complaint[27] at ¶¶ 93-104.

34. Plaintiff claims that, as a result of the Advantage Fit System, she suffered pain, recurrence of incontinence, urinary retention, nerve damage and numbness, recurrence of cystocele, vaginal irritation. *See* Plaintiff Fact Sheet ("PFS")[28] at 6.

## APPLICABLE LAW

For implantable medical device cases that originate elsewhere, this Court applies the choice-of-law rules of the state in which the plaintiff was implanted with the product. *See*

[26] A true and correct copy of the AUA Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of Stress Urinary Incontinence is attached to the Motion as Exhibit T.
[27] A true and correct copy of Master Complaint is attached to the Motion as Exhibit U.
[28] A true and correct copy of excerpts of Ms. Wilkerson's Plaintiff Fact Sheet is attached to the Motion as Exhibit V.

*Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 202787, at *4 (S.D.W. Va. Jan. 17, 2014)[29]; *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, MDL No. 2100, 2011 WL 1375011, at *6 (S.D. Ill. Apr. 12, 2011); *In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, MDL No. 1871, 2012 WL 3205620, at *2 (E.D. Pa. Aug. 7, 2010). Plaintiff's surgery to implant the Advantage Fit System pelvic mesh device occurred in North Carolina. As a result, this Court should apply North Carolina's choice-of-law rules.

North Carolina generally applies the "lex loci delicti" approach. *Harco Nat'l Ins. Co. v. Grant Thornton LLP*, 206 N.C. App. 687, 692, 698 S.E.2d 719, 722-23 (2010). This approach provides that "the state where the injury occurred is considered the situs of the claim." *Id.*, 698 S.E.2d at 722 (quoting *Boudreau v. Baughman*, 322 N.C. 331, 335, 368 S.E.2d 849, 853-54 (1988)). Here, Plaintiff is seeking punitive damages for alleged injuries that occurred in North Carolina. SFC at ¶ 13. Therefore, North Carolina is the place of injury for purposes of Plaintiff's punitive damages claim. Accordingly, North Carolina substantive law applies to Plaintiff's claim for punitive damages.

## SUMMARY JUDGMENT STANDARD

Summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-24 (1986). Summary judgment "is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed to 'secure the just, speedy and inexpensive determination of every action.'" *Celotex*, 477 U.S. at 327 (citations omitted).

[29] All unpublished decisions relied on by Boston Scientific are attached to the Motion as Exhibit W.

Not every factual dispute between the parties will prevent summary judgment. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-49 (1986). Although the Court must review the evidence in the light most favorable to the non-moving party, the non-moving party is required to do more than show some "metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). The non-moving party "may not rest upon the mere allegations or denials of his pleadings, but his response . . . must set forth specific facts showing there is a genuine issue for trial." *Anderson*, 477 U.S. at 248. Conclusory allegations or unsupported speculation is insufficient to preclude the granting of a summary judgment motion. *See Felty v. Graves-Humphreys Co.*, 818 F.2d 1126, 1128 (4th Cir. 1987).

**ARGUMENT**

The recovery of punitive damages in North Carolina is governed by § 1D-15 of the North Carolina General Statutes:

> Punitive damages may be awarded only if the claimant proves that the defendant is liable for compensatory damages and that one of the following aggravating factors was present and was related to the injury for which compensatory damages were awarded:
>
> (1) Fraud
>
> (2) Malice
>
> (3) Willful or wanton conduct.

North Carolina law requires that the defendant's conduct *and its connection to Plaintiff's injury* must be proven by clear and convincing evidence — described as "evidence which should fully convince." *See Schenck v. HNA Holdings, Inc.*, 170 N.C. App. 555, 560, 613 S.E.2d 503, 508 (2005).

Fraud requires proof of: "(1) [f]alse representation or concealment of a material fact, (2) reasonably calculated to deceive, (3) made with intent to deceive, (4) which does in fact deceive, (5) resulting in damage to the injured party." *Wilson, v. Dryvit Sys., Inc.*, 206 F. Supp. 2d 749, 755 (E.D.N.C. 2002), *aff'd*, No. 02-2070, 2003 WL 21805618 (4th Cir. Aug. 7, 2003). In addition, the plaintiff must prove reasonable reliance. *Id.* "Malice" "means a sense of personal ill will toward the claimant that activated or incited the defendant to perform the act or undertake the conduct that resulted in harm to the claimant." N.C. Gen. Stat. § 1D-5(5). "Willful or wanton conduct" is defined as "the conscious and intentional disregard of and indifference to the rights and safety of others, which the defendant knows or should know is reasonably likely to result in injury, damage, or other harm." N.C. Gen. Stat. § 1D-5(7). Such willful or wanton conduct requires "more than gross negligence." N.C. Gen. Stat. § 1D-5(7).

In addition to proving the existence of an aggravating factor, "[p]unitive damages may be awarded against a . . . corporation [only if] the officers, directors, or managers of the corporation participated in or condoned the conduct constituting the aggravating factor giving rise to punitive damages." N.C. Gen. Stat. § 1D-15(c). When no manager has knowledge of an employee's conduct, the corporation cannot be held liable for punitive damages. *Phillips v. Restaurant Mgmt. of Carolina, L.P.*, 146 N.C. App. 203, 216, 552 S.E.2d 686, 694-95 (2001). The manager must either participate in or condone the conduct while it is ongoing. *See, e.g., Wallace v. M, M & R, Inc.*, 165 N.C. App. 827, 833-34, 600 S.E.2d 514, 518 (2004).

Plaintiff's punitive damages claim is deficient and should be dismissed. As a threshold matter, if the Court grants Boston Scientific's Motion for Summary Judgment on Plaintiff's tort claims, then the argument is moot as no punitive damages may be awarded where there are no compensatory damages (on the tort claims), or for contractual breaches of warranty. *McDaniel*

*v. Bass-Smith Funeral Home, Inc.*, 80 N.C. App. 629, 634, 343 S.E.2d 228, 231 (1986) ("Punitive damages are not recoverable for breach of contract, except contracts of marriage, unless the breach also constitutes identifiable tortious conduct, accompanied by some element of aggravation.").

If any of the claims for which Plaintiff seeks punitive damages are permitted to go to the jury for consideration, Plaintiff has not produced evidence of any aggravating factor in connection with any claim. Plaintiff cannot prove that she relied on any allegedly false representation made by Boston Scientific when deciding to undergo surgery with the implant of the Advantage Fit System. *See Wilson*, 206 F. Supp. 2d at 755. Rather, she testified that she relied upon Dr. Booth. *See* Deposition of Hanna Wilkerson ("Ms. Wilkerson Dep.")[30] at 98:13-14. In turn, Dr. Booth relied on her own clinical experience, training, and research, as well as the FDA to offer the best treatment option for Plaintiff. Dr. Booth Dep. at 84:20-85:4, 85:9-20, 99:11-100:8.

Accordingly, Plaintiff has failed to show any basis for a finding of fraud as an aggravating factor.

In addition, other than the conclusory statement in the Master Complaint that "the Defendants' conduct" shows "malice," *see* Master Complaint ¶ 104, Plaintiff has neither alleged, nor could she prove *any* conduct demonstrating "a sense of personal ill will" toward her by any officer, director, or manager at Boston Scientific much less clear and convincing conduct demonstrating malice. *See Shugar v. Guill*, 51 N.C. App. 466, 470, 277 S.E.2d 126, 130 (1981) ("A mere conclusory statement that the wrongful act was advanced in a malicious, wanton, or willful manner is insufficient.").

[30] True and correct copies of excerpts of Ms. Wilkerson's deposition are attached to the Motion as Exhibit X.

Further, as to any claim of willful or wanton conduct, Plaintiff has done no more than rehash the allegations for her other tort claims, which is insufficient to support an award for punitive damages. *See id.* at 469, 277 S.E.2d at 129 (noting that to collect punitive damages "there must be some additional element of asocial behavior which goes beyond the facts necessary to create a simple case of tort").

In *Lashlee v. White Consolidated Industries, Inc.*, 144 N.C. App. 684, 693-694, 548 S.E.2d 821, 827-828 (2001), for example, the plaintiff alleged that defendant demonstrated willful or wanton negligence by making it possible for users of defendant's chainsaws to unknowingly replace a factory-approved low-kickback chain with a non-approved chain. In support of this claim, the plaintiffs pointed to, among other factors, the limited warnings on the chainsaw itself. *Id.* The court rejected the plaintiff's argument that defendant "consciously and recklessly failed to provide consumers with needed information" sufficient to allow the issue of punitive damages to go to a jury based on the opinion of an expert, as the court deemed this to be expert testimony on legal issues. *Id.* at 694, 548 S.E.2d at 827-28.

Similarly here, some of Plaintiff's alleged experts, if allowed to testify, will purportedly opine that Boston Scientific failed to warn of certain risks. Such testimony is nothing more than an attempt to establish the underlying claim of failure to warn. It does not establish any specific conduct of a Boston Scientific officer, manager or director, and is in fact improper expert testimony on a legal issue.

Accordingly, Plaintiff can present no evidence that any officer, manager or director of Boston Scientific acted in accordance with any aggravating factor. Indeed, the evidence is to the contrary. It is uncontroverted that Boston Scientific submitted the Advantage Fit System to the FDA prior to marketing the product, and the FDA cleared them with full knowledge of its

potential benefits and risks, including the information in the MSDS and the medical application caution. According to both Dr. Booth and Plaintiff's retained expert, mid-urethral slings like the Advantage Fit System remain the "standard of care" for treatment like that undergone by Plaintiff. *See* Dr. Booth Dep. at 19:8-20:15; Deposition of William E. Porter, M.D. ("Dr. Porter Dep.")[31] at 234:13-20, 237:14-20. Leading medical societies, in fact, have issued position statements supporting the safety and efficacy of mid-urethral slings like the Advantage Fit Sling.[32] Plaintiff has not and cannot produce any evidence, much less clear and convincing evidence, to support an inference that Boston Scientific's actions warrant punitive damages. Therefore, Boston Scientific is entitled to judgment as a matter of law on the issue of punitive damages.

## CONCLUSION

For all of the foregoing reasons, Boston Scientific respectfully requests this Court grant its Motion for Partial Summary Judgment on Plaintiff's Punitive Damages Claim.

Dated: January 15, 2015

Respectfully submitted,

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**COUNSEL FOR DEFENDANT BOSTON SCIENTIFIC CORP.**

[31] A true and correct copy of excerpts of Dr. Porter's general opinions deposition is attached to the Motion as Exhibit Y.

[32] *See* IUGA Position Statement on Mid-Urethral Slings for Stress Urinary Incontinence; AUGS Position Statement on Mesh Mid-urethral Slings for Stress Urinary Incontinence; AUGS Position Statement on Restriction of Surgical Options for Pelvic Floor Disorders; and AUA Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of Stress Urinary Incontinence, all of which the Court is already well-familiar.

**CERTIFICATE OF SERVICE**

I hereby certify that on January 15, 2015, I caused the foregoing document to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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